



California
Department of
Health Services

SANDRA SHEWRY
Director

State of California-Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

June 28, 2005

N.L.: 18-0605
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TO: ALL CALIFORNIA CHILDREN'S SERVICES (CCS) ADMINISTRATORS,
MEDICAL CONSULTANTS, CHIEF AND SUPERVISING THERAPISTS,
AND STATE CHILDREN'S MEDICAL SERVICES (CMS) BRANCH AND
REGIONAL OFFICE STAFF

SUBJECT: NATIONWIDE RECALL OF VAIL ENCLOSED BED SYSTEMS

The Federal Drug Administration (FDA) has just released the enclosed news bulletin notifying consumers that Vail Products, Inc., Toledo, Ohio, is recalling approximately 5000 "enclosed" bed systems due to associated hazards, injury, and death caused by patient entrapment. Vail Products is permanently ceasing the manufacture, sale and distribution of all "enclosed" bed systems and will no longer be available to provide accessories, replacement parts, or retrofit kits.

Although the FDA has instructed Vail Products, Inc. to notify consumers of this recall, we are uncertain what actions, if any, the company has taken. For these reasons, it is necessary for counties to immediately take the following steps to assure the safety of those children for whom CCS has authorized a Vail "enclosed" bed system:

- Identify all children in your county for whom a Vail "enclosed" bed system was authorized.
- Contact the child's family and determine if the child is still using the bed.
- Issue a copy of the enclosed FDA news bulletin and a copy of FDA's Preliminary Public Health Notification (available at <http://www.fda.gov/cdrh/safety/032505-vail.html>) to each child's family.

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- Ask child's family to have the prescribing physician reevaluate medical necessity for an "enclosed" bed system and consider other alternative interventions that address the child's underlying medical issues.

CCS programs are asked to facilitate this effort by ensuring that authorizations to applicable primary care or specialty providers for these children are in place. A list of known CCS clients who have been authorized for a Vail "enclosed" bed system through EPSDT SS is available through CCS Regional Offices. This is not an all-inclusive authorization list. Other Vail "enclosed" bed systems may have been authorized through straight CCS venues. Please contact your Regional Office Nurse Consultant for information relating to this list.

It is important to document in the CMS Net narrative any family contact regarding this issue and request that families advise CCS if and when Vail Products, Inc. has contacted them. You will be advised at a later date whether or not an alternative "enclosed" bed system will be available for authorization as a replacement for the Vail "enclosed" bed.

If you have any questions, please contact your Regional Nurse Consultant.

Original Signed by Marian Dalsey, M.D., M.P.H.

Marian Dalsey, M.D., M.P.H., Acting Chief
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Enclosure